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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,172	11/30/2001	Jesse J. Twu	LJL 362	9507

23581 7590 11/10/2003

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,172

Applicant(s)

TWU, JESSE J.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 16, and 42-45, drawn to compounds comprised of a labeled species in combination with a metal ion, a peptide or protein and a luminescent label, and kits containing the compounds, classified, for example in several subclasses of classes 435 and 530 based on the structure of the compound.
- II. Claims 13-15, drawn to the compounds of claim 1 in combination with a member(s) of a specific binding pair, classified based on the components of the combination.
- III. Claims 17, drawn to a composition comprised of a luminescent energy donor and a luminescent energy acceptor, classified for example, in class 436, subclass 546.
- IV. Claims 18-21, drawn to a composition comprised of a luminescent energy donor and a luminescent energy acceptor wherein these moieties are covalently bound to a "molecule", classified based on the types of individual components which comprise the mixture.
- V. Claims 22-24, drawn to a composition comprised of a luminescent energy donor and a luminescent energy acceptor wherein these components are attached to complementary specific binding members.
- VI. Claims 25-29, drawn to a method of labeling a species which does not require any of the particulars of Groups I-V.
- VII. Claims 30-35, drawn to a method of detecting energy transfer in a sample.
- VIII. Claims 36-38, drawn to a method of detecting dissociation of a species.
- IX. Claims 39 and 40, drawn to a method of detecting a change in conformation of a species.
- X. Claims 41, drawn to a method of detecting an analyte.

2) The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different compositions are comprised of different combinations of components none of which requires the compound of claim 1 (Group I) as a component.

b) Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed for patentability because novelty may lie in the choice of the particular specific binding pair members. The subcombination has separate utility such as for use in a luminescent ink.

c) Inventions III and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as an indicator of energy transfer in a reaction and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

d) Inventions VI and each of I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group VI does not require any of the particulars of Groups I-V.

e) Inventions VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve different sets of method steps. The methods of Groups VI-IX do not require the use of the compound of Group I and the method of Group X uses a compound T-P-M-L in which the species "T" is unlabeled unlike "T" defined as a "labeled species" in claim 1 (Group I).

3) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring divergent fields of search and different patentability considerations, restriction for examination purposes as indicated is proper.

4) Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5) The claims are generic to an extremely large plurality of disclosed patentably distinct species. A reference which would anticipate or render obvious the compounds of one Group would not necessarily render obvious the members of any other group. For the election of **any** group, Applicant is required under 35 U.S.C. 121 to elect **a single disclosed species**, even though this requirement is traversed. An election of a single disclosed species requires the specific designation of **each and every variable and the attachment points of all variables to each other**. For example, for Group I, a specific definition of each of the variables T, P, M, and L must be made (e.g. a specific amino acid to define T, a specific dye to define L, etc.) and a specific description of how these moieties are attached to each other must be

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made. For a composition comprised of multiple components, a specific definition must be provided for each component. The elected claims will be examined on the merits to the extent that they encompass the elected species and any other species which are not patentably distinct from the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6) Applicant is advised that the compounds encompassed by claim 1 are broad enough to encompass T-P-M-L defined for example as glycine-leucine- Na^+ -green fluorescent protein (where Na^+ is attached to the terminal carboxylic acid of the leucine). Based on the description of the invention as it is set forth in the specification, these compounds are clearly not intended. ***Applicant is encouraged to present claims limited to the elected invention (including elected species) and which contain a description of the point of novelty as it is disclosed in the specification.*** It is noted that the specification contains no description of the "label" which is attached to "T" in claim 1.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

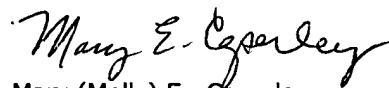
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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November 06, 2003

A handwritten signature in cursive script, reading "Mary E. Ceperley".

Mary (Molly) E. Ceperley
Primary Examiner
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